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Bone Anchor Placement Device With Recessed Anchor Mount

Cross-Reference to Related Applications

This is a continuation-in-part of U.S. Patent Application Serial No. 09/309,816, filed on May 11, 1999, which claims priority to U.S. Provisional Patent Application Serial Nos. 60/085,113, filed May 12, 1998, and 60/125,207, filed March 18, 1999. This is also a continuation-in-part of U.S. Patent Application Serial No. 09/238,654, filed on January 26, 1999, which claims priority to U.S. Provisional Patent Application Serial No. 60/072,641, filed January 27, 1998.

Technical Field

The invention relates generally to devices for placing bone anchors in bone, and in particular, to recessed bone anchor mounts used in connection with bone anchor drivers.

Background Information

Urinary incontinence in women may be caused by urethral hypermobility, a condition in which the bladder neck and proximal urethra may rotate and descend in response to increases in intra-abdominal pressure. Hypermobility may be the result of aging, child delivery or conditions that weaken, stretch, or tear the muscles around the bladder, bladder neck and/or urethra. Urinary incontinence may also be caused by intrinsic sphincter deficiency (ISD), a condition in which the urethral sphincter does not coapt properly.

There are numerous approaches for treating urinary incontinence. In a bladder neck suspension procedure for treating hypermobility, sutures are placed around the muscle groups on either side of the urethra and are affixed to the pubic bone or other supporting structures to reposition and resuspend the proximal urethra. Also common are sling type operations, which may be performed to treat urethral hypermobility, intrinsic sphincter deficiency or both. In a sling type operation, a sling is placed under the urethra and bladder and is tensioned to elevate and stabilize the urethra, prevent excessive downward mobility, or compress the sphincter to treat intrinsic sphincter deficiency.

In these procedures, sutures are anchored to the supporting structures, such as the pubic bone, Cooper's ligament, or the rectus fascia. Bone anchor placement devices, such as bone anchor drivers, may be used to place bone anchors at selected insertion sites in the pubic bone. Sutures may then be attached to the bone anchors.

To reduce postoperative patient discomfort, transvaginal surgical procedures for bone anchor placement are preferred over percutaneous procedures, which require an incision in the abdominal wall (and sometimes the vaginal wall) to introduce a bone anchor placement device, and can be highly invasive and traumatic to the patient. In a transvaginal procedure, vaginal incisions are made and bone anchors or similar attachment devices are secured to the posterior side pelvic wall through the vaginal incision. While being guided to the desired locations, the anchor placement device passes through multiple layers of tissue. During this process, an unprotected bone anchor can catch, tear or scrape tissue, snap a surgeon's glove, or become dislodged.

It is desirable, therefore, to provide a protection mechanism for the bone anchor that prevents the sharp tip of the anchor from causing unintended tissue damage during passage of the anchor through tissue. At the same time, it is desirable that the head design for a bone anchor placement device be as compact as possible to minimize the necessary size of the vaginal incision through which the anchor placement device is inserted.

Summary of the Invention

The present invention relates to manual bone anchor placement devices. The manual bone anchor placement devices disclosed herein are particularly useful in transvaginal methods of treating female urinary incontinence, although they can be used in other medical applications. The devices of the present invention are designed to permit rotational insertion of a bone anchor screw and to provide low cost alternatives to powered cannulated drills. The devices may be disposable or may be modular in nature, thereby allowing interchange of parts for reuse.

An advantage of the disclosed manual bone anchor placement devices is that they eliminate the need for a percutaneous incision to access an insertion area, although the devices can be used in a percutaneous procedure. A transvaginal approach to inserting a bone anchor

screw into the pubic bone is far less invasive than a percutaneous procedure, thus a transvaginal procedure is far less traumatic for the patient.

An additional advantage of the disclosed manual bone anchor placement devices is that they seat a self-tapping bone anchor screw with a pre-attached suture. Since the bone anchor screw used with the disclosed devices is self-tapping and the suture is pre-attached, it is unnecessary for the physician to prebore a hole into the bone, remove the drill, introduce a seating device, seat the bone anchor screw, and then thread the suture. Single-step insertion of the bone anchor screw and suture not only reduces the total time required for the procedure, it also greatly reduces the possibility that the physician may lose access to the bored hole or seated bone anchor screw. Thus, the possible need to drill additional holes and/or seat additional bone anchor screws is reduced.

The manual bone anchor placement devices disclosed herein provide a mechanism to translate linear force exerted by a user on a lever into rotary force on a bone anchor screw. In one aspect of the invention, the manual bone anchor placement device includes a manually actuatable lever, a resilient element, a force translator, and a rotator. The force translator is coupled at its proximal end to the lever and at its distal end to the resilient element. The resilient element is coupled to the rotator. Linear force on the lever is transmitted through the force translator to the resilient element and from the resilient element to the rotator. The rotator rotates in response to this force. The device may further include a securing element coupled to the rotator that mates with a bone anchor screw and rotates when the rotator rotates, thereby applying a torque on the bone anchor screw and placing the bone anchor screw into bone.

In another aspect of the invention, the manual bone anchor placement device includes a manually actuatable lever, a force translator, a rack, and a rotator. The force translator includes a distal end and a proximal end, the proximal end receiving force from the lever, the distal end being coupled to the rack. The force translator transmits force to the rack, which moves linearly into an engaging position in response to this force. The rotator is positioned in close proximity to the rack for engagement with the rack when the rack moves into the engaging position. Engagement of the rotator by the rack causes the rotator to rotate. The device may further include a coupler coupled to the rotator that mates with a bone anchor screw and rotates when the rotator rotates, thereby placing the bone anchor screw into bone.

In another aspect of the invention, a manual bone anchor placement device is disclosed that includes a manually actuatable lever, a driver rod with threads, and a cup and washer positioned over the threads. The cup is coupled to the lever and moves axially along the driver rod upon actuation of the lever, engaging with the washer. When the cup and washer engage each other, linear force transmitted from the lever through the cup is translated to a rotary force on the driver rod, rotating the driver rod. The device may further include a coupling element for mating with a bone anchor screw and for rotating when the driver rod rotates to place the bone anchor screw into bone.

The present invention also relates to a self-tapping buttress-shaped bone anchor screw. The bone anchor screw of the present invention comprises a micropolished eyelet for receiving a suture. The eyelet may be circular, ellipsoidal, or teardrop shaped. The bone anchor screw described herein is designed to require less torque to seat and to minimize load on a pre-attached suture in comparison with known bone anchor screws.

Kits are also disclosed comprising any of: a molded flexible sleeve for enclosing a suture, a retaining clip for preventing the suture from slipping out of the sleeve, a buttress-shaped bone anchor screw comprising a micropolished eyelet for receiving a suture, and a suture which may, or may not, be pre-attached to the bone anchor screw. A collapsible, protective cover for a bone anchor screw is also disclosed.

In yet another aspect of the invention, the manual bone anchor placement device includes a head assembly, a recessed anchor mount movably disposed within the head assembly, and an actuation mechanism coupled to the recessed anchor mount. In various embodiments, the actuation mechanism can be a push wire or a pull wire, and the mechanism actuates the recessed anchor mount between a recessed position and an advanced position. The anchor mount can include an outer surface having at least one flat surface and the head assembly can have a core comprising a mating shape. Further, the manual bone anchor placement device can include a bone anchor releasably engaged to the anchor mount. In addition, the anchor mount can include a groove for accommodating a suture attached to the bone anchor.

In still another aspect of the invention, the manual bone anchor placement device includes a handle, a shaft extending in a distal direction from the handle, a head assembly disposed at a distal end of the shaft, a recessed anchor mount movably disposed within the head assembly, and

an actuation mechanism coupled to the recessed anchor mount. In various embodiments, the actuation mechanism can be a push wire or a pull wire, and the mechanism actuates the recessed anchor mount between a recessed position and an advanced position. Further, the actuation mechanism can be situated within a channel disposed on the handle, an actuator disposed on the handle can operate the actuation mechanism, and the actuation mechanism may be manufactured of spring steel or nitinol. The anchor mount can include an outer surface having at least one flat surface and the head assembly can have a core comprising a mating shape. Further, the manual bone anchor placement device can include a bone anchor releasably engaged to the anchor mount. In addition, the anchor mount can include a groove for accommodating a suture attached to the bone anchor. Still further, the manual bone anchor placement device can include a stop disposed within the head assembly, for example within the core. Alternatively, the stop can be located on the actuation mechanism.

These and other objects, along with advantages and features of the present invention herein disclosed, will become apparent through reference to the following description of embodiments of the invention, the accompanying drawings, and the claims. Furthermore, it is to be understood that the features of the various embodiments described herein are not mutually exclusive and can exist in various combinations and permutations.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis generally being placed upon illustrating the principles of the invention.

Figure 1A is a perspective side view of a manual bone anchor placement device within the scope of the present invention. Figure 1B shows a section of a side-view of the shaft of a manual anchor placement device to which a suture ring is clipped and through which a suture is threaded. Figure 1C shows an enlarged cross-sectional view of a suture ring.

Figure 2 shows a perspective side view of a manual bone anchor placement device according to one embodiment of the present invention. In this embodiment, the manual bone anchor placement device comprises a groove cut into the outer surface of the handle through which a suture is threaded and the shaft of the manual bone anchor placement is angled upwards at about a 90-degree angle.

Figure 3A is a side view of a cross-section through a wrap-around manual bone anchor screw placement device according to one embodiment of the invention showing the components of an action mechanism and a wrap-around rotary force mechanism in which a resilient element is wrapped around a rotator. Figure 3B is an enlarged perspective view of a connector and lever arrangement in an action mechanism according to one embodiment of the invention.

Figures 4A-4D show views of the head end of a wrap-around manual bone anchor placement device according to different embodiments of the invention. Figure 4A shows a cross-sectional view of an embodiment where the rotator includes a floating pawl. Figure 4B shows an enlarged cross-sectional view of a rotator that has three floating pawls. Figure 4C shows a three-dimensional cut-away view of the head end of the shaft in an embodiment of the invention where the rotator has two floating pawls. Figure 4D shows a three-dimensional cut-away view of the head end of the shaft in an embodiment of the invention where the rotator has a single floating pawl.

Figures 5A-5H show enlarged views of securing elements used with a wrap-around manual bone anchor placement device and bone anchor screws according to different embodiments of the invention. Figures 5A-5D show enlarged views of a securing element that has a hex-shaped recess in its mating portion for mating with a bone anchor screw with a hex-shaped shaft at its base. Figure 5A is a perspective view of the securing element showing the hex-shaped recess. Figure 5B is a cross-sectional view through the engaging portion of the securing element. Figure 5C is a perspective side-view of the securing element. Figure 5D is a view from the top of the securing element. Figure 5E shows a bone anchor screw that has a hex-shaped shaft at its base. Figure 5F shows a perspective view of a securing element whose mating portion has a hex-shaped protrusion. Figure 5G shows a perspective side view of a securing element whose mating portion has a hex-shaped protrusion. Figure 5H shows an enlarged view of a bone anchor screw with a hex-shaped recess at its base for mating with a securing element whose mating portion has a hex-shaped protrusion.

Figures 6A-6C show enlarged views of the rotatable housing used in a wrap-around manual bone anchor placement device. Figure 6A shows a perspective view. Figure 6B shows a side view. Figure 6C shows a cross-sectional view.

Figures 7A-7C show enlarged views of the floating portion of a floating pawl used in a wrap-around manual bone anchor placement device. Figure 7A shows a perspective view. Figure 7B shows a side view. Figure 7C shows a cross-sectional view.

Figures 8A-8C show enlarged views of the flat spring portion of a floating pawl used in a wrap-around manual bone anchor placement device. Figure 8A shows a perspective view where the flat spring portion is slightly bent. Figure 8B shows a side view of a flat spring portion that is slightly bent. Figure 8C shows a perspective view where the flat spring portion is lying flat.

Figure 9 shows an enlarged view of a resilient element used in a wrap-around manual bone anchor screw placement device.

Figure 10 shows a schematic view of how force is transmitted through the resilient element in a wrap-around manual bone anchor placement device.

Figure 11 shows a perspective view of a wrap-around manual anchor placement device according to one embodiment of the invention where the shaft and handle portions include interchangeable modules.

Figures 12A-12I show enlarged views of a head module of a wrap-around manual bone anchor placement device according to one embodiment of the invention.

Figure 13A shows an enlarged perspective view of a head module of a wrap-around manual bone anchor placement device according to one embodiment of the invention where a protective sheath is provided to protect the bone anchor screw and the portion of the securing element that protrudes from the head module. Figure 13B shows an enlarged perspective view of a collapsible protective cover for a bone anchor screw. The left-hand side of the Figure shows the cover in an uncollapsed state. The right-hand side of the Figure shows the cover in a collapsed state. Figure 13C shows an enlarged cross-sectional view of a collapsible protective cover surrounding a bone anchor screw. The left-hand side of the Figure shows the cover in an uncollapsed state and completely surrounding a bone anchor screw. The right-hand side of the Figure shows the cover in a collapsed state, exposing the bone anchor screw.

Figure 14 shows an enlarged version of a securing element used in a wrap-around manual bone anchor placement device according to one embodiment of the invention where the mating portion of the securing element may be uncoupled from the engaging portion of the securing element.

Figure 15 is a side view of a cross-section through a rack and rotator manual bone anchor placement device according to one embodiment of the invention, showing the components of an action mechanism and a rack and rotator rotary force mechanism.

Figure 16 shows an enlarged view of a head assembly in a rack and rotator manual bone anchor screw placement device in which the rotator comprises a ratchet wheel.

Figure 17 shows an enlarged view of a head assembly in a rack and rotator manual bone anchor placement device in which the rotator comprises a pinion.

Figures 18A and 18B show a side view of a cross-section through the handle and proximal portion of the shaft in a rack and rotator manual bone anchor placement device according to one embodiment of the invention. Figure 18A shows an action mechanism that transmits a pull force on a force translator. Figure 18B shows an action mechanism that transmits a push force on a force translator.

Figure 19 shows an enlarged cross-sectional view of a head assembly in a rack and rotator manual bone anchor placement device according to one embodiment of the invention, in which linear force is transmitted to the rack through a rack spring and the rotator comprises a pinion. A bone anchor screw with a pre-attached suture is shown coupled to the pinion by a coupler. A protective cover covers the bone anchor screw. Dashed lines in the Figure show the portion of the bone anchor screw and pre-attached suture inside the coupler.

Figure 20 shows an enlarged cross-sectional view of a head assembly in a rack and rotator manual bone anchor placement device according to one embodiment of the invention in which linear force is transmitted to the rack via wedge members.

Figure 21 shows an enlarged cross-sectional view of a head assembly in a rack and rotator manual bone anchor placement device according to one embodiment of the invention in which linear force is transmitted to the rack by pneumatic or hydraulic force on a plunger.

Figure 22A shows a cross-sectional sideview of a cup and washer manual bone anchor placement device according to one embodiment of the invention that includes a cup and washer rotary force mechanism. Figure 22B shows a further embodiment of the invention in which a return coil spring is provided between the cup and washer assembly and the barrel end of the handle.

Figures 23A-23D show enlarged views of a cup and washer assembly used in a cup and washer manual bone anchor placement device according to one embodiment of the invention. Figure 23A shows a cross-sectional view of a driver rod with grooves to interface with protrusions on a washer. Figure 23B shows a cross-sectional view of a washer with corresponding protrusions to interface with the grooves in the driver rod. Figure 23C shows a perspective side view of a cup and washer assembly on a driver rod in which the washer is in a "free-floating" or non-engaged position. Figure 23D shows a perspective sideview of a cup and washer assembly in which the washer is in an engaged position.

Figures 24A and 24B show enlarged views of a cup and washer assembly according to one aspect of the invention. Figure 24A shows a cross-sectional view from one side of a cup and washer assembly positioned on a driver rod that includes a cover plate. Figure 24B shows a cross-sectional view from the top of the cup and washer assembly.

Figure 25A shows a section of a lead anchor screw and a coupling element used in a cup and washer manual bone anchor placement device according to one embodiment of the invention in which the coupling element has a recess through which the suture of a bone anchor screw is threaded. The Figure shows the suture partly pulled out of the recess. Figure 25B shows a perspective view of the top of a cover plate used in a cup and washer assembly according to one embodiment of the invention. Figure 25C shows a perspective view of the top of a washer used in a cup and washer assembly. Figure 25D shows a perspective view of the top of a cup used in the cup and washer assembly (i.e., the side that faces the washer).

Figure 26 shows a cross-section through a longitudinal axis of a self-tapping bone anchor screw according to one embodiment of the invention.

Figure 27A is a side view of an alternate embodiment of an anchor placement device constructed according to the present invention.

Figures 27B-27E are cross-sectional views of various embodiments of the shaft of the device of Figure 27A as taken at A-A.

Figure 28A is an enlarged perspective view of one embodiment of an anchor mount constructed according to the present invention and of a bone anchor for attachment to the anchor mount.

Figures 28B and 28C are end views of alternate embodiments of an anchor mount constructed according to the present invention.

Figure 29A is an enlarged view of one embodiment of the head assembly of the anchor placement device of Figure 27A, and of a recessed anchor mount in a recessed position within the head assembly.

Figure 29B is an enlarged view of one embodiment of the head assembly of the anchor placement device of Figure 27A, and of a recessed anchor mount in an advanced position protruding from the head assembly.

Figure 29C is an enlarged view of a push wire in point contact with the anchor mount of Figure 29A

Figure 29D is an enlarged view of a push wire secured to the anchor mount of Figure 29A.

Figure 30A is a side view of an alternate embodiment of the anchor placement device depicted in Figure 27A.

Figure 30B is an enlarged view of one embodiment of the head assembly of the anchor placement device of Figure 30A, and of a recessed anchor mount in a recessed position within the head assembly.

Detailed Description

The manual bone anchor placement devices disclosed provide a mechanism to translate manual linear force (i.e., an operator's hand squeezing a lever) into rotary force on a bone anchor screw. As used herein "placing a bone anchor screw" (or grammatical equivalents thereof) refers to rotational action on, and/or screwing in, of a bone anchor screw into bone. Manual actuation of the disclosed devices occurs when the operator squeezes or pulls a lever with, for example, a single hand. Force on the lever is mechanically transmitted through a force translator to a rotary force mechanism. Each of the disclosed devices is distinguishable by the type of rotary force mechanism used.

In one aspect of the invention, a manual bone anchor placement device uses a rotary force mechanism that includes a resilient element wrapped around a rotator ("wrap-around manual bone anchor placement device"). In a second aspect of the invention, a manual bone anchor

placement device ("rack and rotator manual bone anchor placement device") uses a rotary force mechanism that includes a rack and rotator assembly. In a third aspect of the invention, a manual bone anchor placement device uses a rotary force mechanism that includes a cup and washer assembly ("cup and washer manual bone anchor placement device"). A self-tapping bone anchor screw with a pre-attached suture is also disclosed, which may also be used with any of the aforementioned manual bone anchor placement devices. In addition, a recessed bone anchor mount is disclosed, which may be used with any of the aforementioned manual bone anchor placement devices. All of the devices are useful in, for example, transvaginal bone anchor screw insertion procedures.

Wrap-Around Manual Bone Anchor Placement Device

In the embodiment of the invention shown in Figure 1, the manual bone anchor placement device **1** is substantially pistol- or gun-shaped. In this embodiment, the manual bone placement device **1** includes a handle **2** and a shaft **3**. The handle **2** has a gripping portion **26** to facilitate gripping by the user and a lever **4** through which the user may manually transmit force to the bone anchor placement device **1**.

As shown in Figure 3A, the shaft **3** has a first end **3a**, proximal to the handle **2**, and a second end or head end **3h**, distal to the handle **2**. A force translator **12** runs through the shaft **2** and transmits linear force exerted manually on the lever **4** to a head assembly **35** positioned at the second end **3h** of the shaft **3** (shown enlarged in Figure 4A). The head assembly **35** is capable of engaging with a bone anchor screw **5** and includes the mechanism that translates linear force from the force translator **12** to rotary force on the bone anchor screw **5**.

The shaft **3** is curved to facilitate correct placement of the bone anchor placement device **1** to the proper bone anchor screw insertion site. The shaft **3** is generally linear at its proximal or first end **3a** and angles upward near its head end **3h**. The upward angle can be from about 0 degrees to about 135 degrees. In one embodiment of the invention, the upward angle is between about 75 degrees and about 100 degrees. In another embodiment of the invention, shown in Figure 2, the upward angle is approximately 90 degrees. In some embodiments of the invention, the shaft **3** can be rotated about 360 degrees relative to the handle **2** (see dashed arrow in Figure 1A).

As shown in Figure 3A, the handle **2** of the manual bone anchor placement device **1** of the present invention may further include an action mechanism through which force from the lever **4** is transmitted to the force translator **12**. The action mechanism includes the lever **4**, a pivot **9,** and the proximal end of the force translator **12**. The force translator **12** is connected to the lever **4** by a connector **11** that is positioned beneath the pivot **9**. The action mechanism further includes a torsional spring **10** that abuts the lever **4** in the handle **2**.

In an embodiment of the invention shown in Figure 3B, the connector **11** has a "slot and pin arrangement." In this embodiment, a slot **11s** is included in the portion of the lever **4** proximal to the pivot **9** and defines openings in the sides, front, and back of the lever **4**. A connector member **11m** is configured to fit in the slot **11s** and includes a pinhole **11h**. The connector member **11m** is coupled to the force translator **12** at the end of the connector member **11m** distal to the pinhole **11h.** The connector member is positioned within the slot **11s** and secured by a pin **11p** that extends through both the slot **11s** and the pinhole **11h**.

In the embodiment of the invention shown in Figure 3A, the lever **4** extends at least partially from the handle **2** and linear force on the lever **4** is exerted by pulling on the lever **4**. Because the pivot **9** is located above the connector **11**, the translator **12** is subjected to tensile loading (e.g., a pulling force) during activation and compressive loading (e.g., a pushing force) during release. The torsional spring **10** abutting the lever **4** thus forces the lever **4** into its original position for the next stroke.

Force exerted on the lever **4** is translated as linear force through the force translator **12**. As shown in Figure 3A, the force translator **12** is a substantially linear member that extends from the handle **2** through the shaft **3** of the manual bone anchor device **1**. The force translator **12** may be rigid or flexible, so long as it is tensile. In one embodiment of the invention, the force translator **12** is a wire. Additional types of force translators **12** include, but are not limited to, a cable, a rod, suture material, a string, and the like. Suitable force translator **12** materials include metal, plastic, polymers (e.g., nylon, in the case of suture materials), copolymers, and the like.

In a further embodiment of the invention, washers **21** are positioned on the inside of the shaft **3** to reduce the friction caused by the force translator **12** contacting the inside surfaces of the shaft **3** (see Figure 4A). The washers **21** can be made of Teflon® material or any material with a low coefficient of friction.

The section of the shaft portion that seats the head assembly **35** may be simply a wider extension of the head end **3h** of the shaft **3** shown in Figure 3A. Alternatively, the head assembly **35** may be provided within a head module **28** seated on the distal-most tip **3b** of the shaft (as in Figures 4A, 4C, and 4D, for example) and may be either integral with the shaft **3** or separable from the shaft **3**. The head assembly **35** includes a rotator **14,** a securing element **166,** and a resilient element **13**, shown in more detail in Figures 4A-4D. The resilient element **13** is coupled to both force translator **12** and the rotator **14**. In one embodiment of the invention, as shown in Figures 4C and 4D, the resilient element **13** is a constant force spring that is welded to the end of the force translator **12** that is proximal to the rotator **14**.

Force is transmitted through the resilient element **13** to the rotator **14,** which rotates in response to this force. The rotator **14** has at least one protruding portion **15p,** shown in more detail in Figures 4C and 4D, and is capable of frictionally and mechanically engaging with the securing element **166** (shown in more detail in Figures 5A, 5C, 5F, and 5G). The securing element **166** further includes an engaging portion **16** and a mating portion **6**. The mating portion **6** of the securing element **166** extends at least partly from the head end **3h** of the shaft **3,** or the head module **28,** and mates with a bone anchor screw **5**.

In the embodiment of the invention shown in Figures 4A-4C, the rotator **14** has at least one floating pawl and the engaging portion **16** of securing element **166** has teeth **17** that are capable of meshing with the protruding portion **15p** of the floating pawl and rotating in response to the rotation of the pawl. The protruding portion **15p** extends from a flat spring member **15s** as shown in Figures 4C and 4D. The flat spring member **15s** may be angled or bent, as shown in more detail in Figures 8A-8C, to control the position of the protruding portion **15p** of the pawl.

It will be readily apparent to one of ordinary skill in the art that any number and type of protruding portions **15p** may be provided so long as they are able to frictionally and mechanically engage with the engaging portion **16** of the securing element **166** to cause rotation of the securing element **166**. In the embodiment of the invention shown in Figure 4B, the rotator **14** includes three floating pawls that are spaced equidistant from each other about a central axis of rotation. In another embodiment of the invention, shown in Figure 4C, the rotator **14** includes two floating pawls, and the teeth **17** of the engaging portion **16** are designed to allow one-directional

engagement with the pawls. Slip-free rotation of a bone anchor screw **5** is provided by this design.

In the embodiment of the invention shown in Figures 4C and 4D, the rotator **14** is contained within a rotatable housing **18** positioned within the head module **28** and is fitted into at least one groove **22** within the inner wall of the rotatable housing **18**. Figures 6A-6C show enlarged views of the rotatable housing **18**. In the embodiment of the invention shown in Figures 6A and 6C, the rotatable housing **18** has two grooves **22** to accommodate a rotator **14** that includes two floating pawls.

In the embodiment of the invention shown in Figures 4A-4D, the resilient element **13** is at least partially wound around the rotatable housing **18**, and the rotatable housing **18** and the rotator **14** move as one. The resilient element **13** is secured to the rotatable housing **18** by the insertion of an inwardly projecting tail **13t** of the resilient element **13** into a notch **25** in the rotatable housing **18**. An enlarged view of the resilient element **13** and inwardly projecting tail **13t** is shown in Figure 9.

As shown schematically in Figure 10, force transmitted through the resilient element **13** causes the inner diameter **ID** of the resilient element **13**, which is wrapped around the rotatable housing **18,** to decrease and the resilient element **13** to grip the rotatable housing **18**, resulting in its rotation. Upon elimination of force on the resilient element **13**, the inner diameter **ID** of the portion of the resilient element **13** wrapped around the rotatable housing **18** gets larger, resulting in free rotation in the opposite direction. The gripping action in one direction and the slipping action in the opposite direction provide the action needed to drive a bone anchor screw **5** into the bone when a linear pull force is exerted on the lever **4**.

In the embodiment of the invention shown in Figures 4C and 4D, the securing element **166** is positioned at least partially within the rotatable housing **18**, and the engaging portion **16** of the securing element **166** rotates in response to the rotation of the rotatable housing **18** and rotator **14**.

As shown in the enlarged view of the securing element **166** provided in Figures 5A and 5C, the securing element **166** further includes a generally cylindrical front piece **19** that extends from the engaging portion **16** of the securing element and fits into a complementary recessed portion **30** in the inner wall of the head end **3b** of the shaft **3** or the head module **28** (shown in

Figures 12A, 12B, and 12C). The front piece **19** acts to position the rotatable housing **18** within the head end **3h** of the shaft **3** or within the head module **28** (as shown in Figures 12A, 12B, and 12C), allowing it to rotate freely about the axis defined by the front piece **19**.

The mating portion **6** of the securing element **166** extends at least partially outside the head end **3h** of the shaft **3**. The bone anchor screw **5** may be seated on the mating portion **6** of the securing element **166** in a variety of ways and the mating portion **6** of the securing element **166** may be fabricated to complement a variety of different types of bone anchor screws **5**. In one embodiment of the invention, shown in Figure 5E, when the bone anchor screw **5** being used provides a shaft **5a** with a hex-shape, the mating portion **6** of the securing element **166** is designed to provide a recess **6a** that has a hex-shaped cross-section (see Figures 5A, 5B, and 5D). It will be readily apparent to one of ordinary skill in the art that the recess **6a** of the mating portion **6** of the securing element **166** may be any type of shape (e.g., a T-shape or an X-shape) that allows for frictional and mechanical engagement with a bone anchor screw **5** having a shaft **5a** with the corresponding shape. In a further embodiment of the invention, shown in Figures 5F and 5G, the mating portion **6** of the securing element **166** has a shaft **6b** while the bone anchor screw **5** (shown in Figure 5H) provides a recess **5b** complementary to the shape of the shaft **6b**

Any type of bone anchor screw **5** may be used adaptable to the mating portion **6** of a selected securing element **166**. In one embodiment, shown in Figure 1A, the bone anchor screw **5** has a pre-attached suture **7** and the walls of the shaft **3** defining the head end **3h** of the shaft have aligned openings **20a** and **20b** through which the suture **7** is threaded. (Aligned openings may also be provided in the head module **28** in embodiments of the invention where the bone anchor placement device comprises a head module **28**.) Attachment of the suture **7** along the length of the shaft **3** will keep the suture **7** from becoming entangled during the bone anchor screw insertion procedure.

In the embodiment of the invention shown in Figures 1A-1C, the length of the suture **7** extending out of the head end **3h** of the shaft **3** may be secured by one or more suture rings **8** mounted on the shaft **3**. The suture rings **8** may be an integral part of the shaft **3** or may be clipped on as shown in Figure 1B. After the bone anchor screw **5** is seated, the bone anchor screw **5** disengages from the mating portion **6** of the securing element **166**. The suture **7** then

slips through aligned openings **20a** and **20b** at the head end **3h** of the shaft **3** and through the suture rings **8**, disengaging from the bone anchor placement device **1**.

In another embodiment of the invention, shown in Figure 2, a groove **23** is cut into the outer surface of the handle **2**, extending in a line parallel to the longitudinal axis of the shaft **3**, which is proximal to the gripping portion **26** of the handle **2**. In this embodiment of the invention, the suture **7** is enclosed within a flexible, molded sleeve **24**, composed of Teflon® material, for example, which is press-fitted into the groove **23** of the handle **2**. In a further embodiment of the invention, a retaining clip **27** may be provided at the end of the sleeve **24** proximal to the gripping portion **26** of the handle **2** to prevent the suture **7** from slipping out before the bone anchor screw **5** is screwed into the bone. The user of the manual bone anchor placement device **1** may then cut the retaining clip **27,** which allows the suture **7** to slide out of sleeve **24** after the bone anchor **5** is screwed into the bone.

In further embodiments of the invention, the manual bone anchor placement device **1** may be fabricated from modules including a handle module and a shaft module, allowing the user to mix and match different handles **2** with different shafts **3** (including different head assemblies **35**). In the embodiment of the invention shown in Figure 11, the handle module comprises the two halves **2a** and **2b** of the handle **2** (including the two halves **26a** and **26b** of the gripping portion **26**) that are separable from each other. In this embodiment, an old shaft **3o** may be removed from the handle **2** upon disconnecting the force translator **12** from the connector **11**. A new shaft **3nu** may then be positioned within the handle **2**. After connecting the force translator **12** of the new shaft **3nu** to the connector **11**, the two halves **2a** and **2b** of the handle **2** are snapped back together and the wrap-around manual bone anchor placement device **1** is ready for use.

In the embodiment shown in Figure 11, interchanging the old shaft **3o** from the original bone anchor placement device **1** with a new shaft **3nu** provides the user with the opportunity to replace a shaft **3** with an approximately 30 degree upward angle with one with an approximately 90 degree upward angle and a different type of head end **3h**. The modular nature of the wrap-around bone anchor placement device **1** thus allows users to select the type of shaft **3** or head end **3h**/head module **28**/head assembly **35** that best suits their needs and facilitates repairs of the device **1.**

As shown in Figures 12A-12I, the front half **28f** and back half **28b** of the head module **28** may also be separated by unscrewing screws at coupling regions **33**. This allows the user to vary the exact configuration of the head module **28** and head assembly **35** being used with a particular shaft **3**.

In the embodiment shown in Figures 12E, 12G, and 12H, the front half of the head module **28f** may also be provided with a protruding threaded element **31**. As shown in Figure 13A, a protective cover **32** may be seated on this threaded element **31**, providing a covering for the bone anchor screw **5** extending outside of the head module through opening **36** and protecting the tip of the bone anchor screw **5** from damage before it contacts a bone insertion site. In a further embodiment of the invention, shown in Figures 13B and 13C, the protective cover for protecting a bone anchor screw has a base **32b** for engaging the shaft **3** of the manual bone anchor placement device **1**, and a sheath **32s** coupled to the base **32b** for surrounding and protecting the bone anchor screw **5**. The sheath **32s** is collapsible and collapses as the bone anchor screw **5** is driven into bone, thereby uncovering the bone anchor screw **5**. Sheath **32s** materials include flexible plastic, rubber, thin pleated metal, and the like.

In still a further embodiment of the invention, shown in Figure 14, the mating portion **6** of the securing element **166** may be uncoupled from the engaging portion **16** of the securing element **166** without opening the head end **3h** or head module **28**. In this embodiment of the invention, the mating portion **6** of the securing element **166** is threaded onto a threaded element **34** that protrudes from the engaging portion **16** of the securing element **166** and may be unscrewed from the engaging portion **16** of the securing element **166**. This embodiment of the invention allows different types of mating portions **6** to be coupled to the engaging portion **16** of the securing element **166** and thus allows the user to select a mating portion **6** of a securing element **166** that is complementary to any desired type of bone anchor screw **5**.

<u>Rack and Rotator Manual Bone Anchor Placement Device</u>

As shown in Figure 15, the rack and rotator manual bone anchor placement device **36**, like the wrap-around device **1**, is substantially pistol- or gun-shaped and includes a handle **2** and a shaft **3**. The handle **2** includes a gripping portion **26** and a lever **4** through which a user may manually transmit linear force to the rotary force mechanism of the device **36**. Like the wrap-

around device **1,** the shaft **3** of the rack and rotator manual bone anchor placement device **36** has a first end **3a** proximal to the handle **2**, and a second end, or head end **3h**, distal to the handle **2**.

As in the wrap-around device **1**, the shaft **3** of the rack and rotator manual bone anchor placement device **36** is curved to facilitate correct placement of the bone anchor placement device **36** to the proper bone anchor screw insertion site, angling upward near its head end **3h**. The upward angle can be from about 0 degrees to about 90 degrees. In one embodiment of the invention, the upward angle is between about 35 degrees and about 60 degrees. In the embodiment of the invention shown in Figure 15, the upward angle is approximately 45 degrees. The upward angle of the shaft **3** may be optimized to facilitate insertion of a bone anchor screw **5**. The shaft **3** can also be rotated about 360 degrees relative to the handle portion **2** (see dashed arrow in Figure 15).

As in the wrap-around manual bone anchor placement device **1**, the rack and rotator manual bone anchor placement device **36** has an action mechanism through which force on the lever **4** is transmitted to the force translator **12**. The action mechanism includes lever **4**, pivot **9,** and the proximal end of the force translator **12**. A torsional spring **10** abuts the lever **4** in the handle **2**. The force translator **12** is connected to the lever **4** by a connector **11**, but the position of the connector **11** relative to the pivot **9** may be varied. As in the wrap-around manual bone anchor device **1**, the force translator **12** may be rigid (e.g., a rod) or flexible (e.g., a spring, wire, string, suture material, or the like).

Unlike the wrap-around bone anchor placement device **1**, in which a pushing force is transmitted to the force translator **12** by squeezing the lever **4** towards the gripping portion **26** of the handle **2**, the rack and rotator bone anchor placement device **36** may be configured so that either a push force or a pull force may be transmitted through the force translator **12** by squeezing the lever **4**.

In the "pull" embodiment, shown in Figure 18A, pivot **9** is positioned above connector **11**. In this embodiment, mechanical actuation of the lever **4** causes the force translator **12** to be subjected to tensile loading, i.e., a pulling force, when the user squeezes the lever **4** toward the gripping portion **26** of the handle **2**, and compressive loading when the user releases the lever **4**.

In the "push" embodiment shown in Figure 18B, pivot **9** is positioned below connector **11** which connects force translator **12** to the lever **4**. Squeezing the lever **4** in this embodiment causes the force translator **12** to be subjected to compressive loading, or a pushing force.

Force translator **12** runs through the shaft **3** and transmits linear force exerted manually on the lever **4** to a head assembly **37** positioned at the head end **3h** of the shaft **3**. Washers **21** positioned on the inside of the shaft **3** reduce the friction caused by the force translator **12** contacting the inside surfaces of the shaft **3** (see Figure 15).

Head assembly **37** includes a rack **38** and a rotator **14**. The rotator **14** includes at least one protruding portion **15p**, and a coupler **43**. Head assembly **37** performs a similar function in the rack and rotator bone anchor placement device **36** as head assembly **35** does in the wrap-around device **1**, translating linear force from the force translator **12** to rotary force on a bone anchor screw **5**, but does so through a different mechanism.

As shown in Figure 16, the distal end of the force translator **12** is coupled to rack **38**, which is positioned proximal to rotator **14.** The rack **38** is only able to move in the y direction while the rotator **14** is only able to move rotationally about the x-axis. When the rack **38** moves into an engaging position relative to the rotator **14**, the teeth of rack **38** mesh with the protruding portion **15p** of rotator **14,** causing the rotator **14** to rotate. Thus, linear force transmitted through the force translator **12** translates into movement of the rack **38** along the y-axis, which in turn translates into rotation of the rotator **14** about the x-axis. The rotator **14** is coupled to coupler **43,** which is capable of mating with or engaging a bone anchor screw **5**. Rotation of the rotator **14** is translated into a torque applied on the coupler **43**, which in turn drives or screws a bone anchor screw **5** into bone. Rotators **14** that may be used with racks **38** of the present invention include ratchet wheels, pawls, pinions, gears, and the like.

In the embodiment of the invention shown in Figure 16, the rotator **14** is a ratchet wheel. In this embodiment of the invention, the interior of the head end **3h** of the shaft **3** comprises a grooved element **40** that includes an actuating groove **41** and a return groove **42**. A head assembly spring **39** is also positioned within the head end **3h** and is coupled by a first end **39f** to the inner wall of the head end **3h** of the shaft **3** distal to rack **38** and at a second end **39s** to force translator **12**. Squeezing lever **4** exerts a linear pull force on the translator **12,** which mechanically pulls the rack **38** along the actuating groove **41** towards the rotator/ratchet wheel

14. When the rack **38** reaches an engaging position it engages the protruding portions **15p** of the rotator/ratchet wheel **14** and rotates the rotator/ratchet wheel **14,** which in turn rotates coupler **43.** Coupler **43** engages or mates with a bone anchor screw **5**, and rotation of the coupler **43** applies a torque on the bone anchor screw **5**, thereby screwing it into bone.

Release of lever **4** by the operator transmits a compressive force through the force translator **12** (in this embodiment, a flexible wire) to the head assembly spring **39**. A push force exerted by head assembly spring **39** in response to this compressive force forces the rack back into return groove **42** during the return stroke and disengages the rack **38** from the rotator **14**.

The rack and rotator rotary force mechanism shown in Figure 16 may also be adapted for a push embodiment. In a push embodiment, compressive loading on the force translator **12** forces the rack **38** forward to engage the rotator/ratchet wheel **14,** which rotates in response to this engagement. The rotation of the rotator/ratchet wheel **14** rotates coupler **43**, which in turn applies torque on a bone anchor screw **5**. By varying the position of the connector **11** relative to the pivot **9** in the action mechanism as shown in Figures 18A and 18B, the device **36** may be configured to be used in either a pull or push embodiment.

In the embodiment of the invention shown in Figure 17, the rotator **14** is a pinion. Rotary motion from the rotator/pinion **14** is transmitted to a bone anchor screw **5** through coupler **43,** which extends at least partially through the head end **3h** of the shaft **3** through opening **200a**. A push force or a pull force may be transmitted through the force translator **12**, as discussed above, by varying the position of the connector **11** relative to the pivot **9** in the action mechanism of the device **36**. A rotator spring **44** provides an opposing force to return the rotator/pinion **14** to its original position. In the embodiment of the invention shown in Figure 17, the bone anchor screw **5** is pre-attached to a suture **7**, and both the coupler **43** and the rotator/pinion **14** have openings through which the suture **7** is threaded**.** The suture **7** dangles from the head end **3h** of shaft **3** through opening **200b**.

Figure 19 shows an embodiment of the invention in which the rotator **14** is a pinion, and a compressive force, or push force, is transmitted on a force translator **12**. An opposing compressive force is provided by rack spring **45**, shown in cross-section in the Figure, that encircles the end of the force translator **12** proximal to rack **38** and forces the rack **38** back to its original position during a release stroke.

Figure 20 shows a further embodiment of the invention in which the force translator **12** includes a first wedge member **46** at the end of the force translator **12** distal to the rack **38**. In this embodiment, the force translator **12** is not directly coupled to the lever **4,** but terminates substantially at the neck **47** of the head end **3h** of the shaft **3**. The translator **12** receives force from a tubular member **48** that terminates in a second wedge member **49** and is connected to the lever **4** at connector **11**. Actuation of the lever **4** pushes the second wedge member **49** against the first wedge member **46** and transmits a compressive force, i.e., a push force, to the force translator **12**. During the release stroke, rotator spring **44** forces the rotator/pinion **14** back to its original position while rack spring **45** forces the rack **38** into its initial position.

Figure 21 shows a further embodiment of the invention in which hydraulic or pneumatic pressure is used to exert a compressive, or push force, on a force translator **12p**. In this embodiment of the invention, the force translator **12p** is a plunger positioned in close proximity to the rack **38**. An o-ring **50** maintains a seal separating air or fluid in the shaft **3** from the rack **38** and rotator/pinion **14** assembly. Hydraulic or pneumatic forces transmitted through the shaft **3** upon actuation of the lever **4** drive the plunger **12p** forward, transmitting linear force from the plunger **12p** to the rack **38**, which is in turn pushed forward to engage the rotator/pinion **14**. The rotator/pinion **14** rotates and transmits rotary force to coupler **43**, which applies a torque to a bone anchor screw **5.** Opposing compression forces from rotator spring **44** forces the rotator/pinion **14** back to its original position while rack spring **45** forces the rack **38** to return to its initial position.

As will be readily apparent to those of ordinary skill in the art, many of the features of the wrap-around manual bone anchor placement device **1** may be adapted for use with the rack and rotator manual bone anchor placement device **36**. For example, a suture **7** pre-attached to a bone anchor screw **5** may be clipped to the shaft **3** by suture rings **8** to keep the suture **7** from becoming entangled during the bone anchor screw **5** insertion procedure. Alternatively, the suture **7** may be enclosed within a flexible, molded sleeve **24** press-fitted into a groove **23** cut into the handle **2.** A retaining clip **27** provided at the end of the sleeve **24** proximal to the gripping portion **26** of the handle **2** may be provided to prevent the suture **7** from slipping out of the sleeve **24** before the bone anchor screw **5** is screwed into bone.

The coupler **43** may also be configured to be adapted to a wide variety of bone anchor screws **5**. Like the securing element **166** of the wrap-around bone anchor placement device **1**, the coupler **43** of the rack and rotator manual bone anchor placement device **36** includes a mating portion **43m** that extends at least partially outside head end **3h** of the shaft **3** and which can be fabricated to complement different types of bone anchor screws **5**. In the embodiment of the invention shown in Figure 19, the coupler **43** provides a mating portion **43m** that is a hex-shaped recess that seats a bone anchor screw **5** with a hex-shaped shaft **5a**, (e.g., as shown in Figure 5E). The mating portion **43m** of the coupler **43** may be configured in any type of shape (e.g., shaft or recess) that allows for frictional and mechanical engagement with a bone anchor screw **5** having the corresponding shape (e.g., recess or shaft).

As with the wrap-around manual bone anchor placement device **1**, a protective cover **32** may be provided to protect the tip of the bone anchor screw **5** from damage before it contacts a bone insertion site, and may be collapsible to expose the bone anchor screw **5** only when it contacts the bone.

As with the wrap-around manual bone anchor placement device **1**, the rack and rotator bone anchor placement device **36** may be fabricated in a modular configuration to provide for the ready interchange of different head modules and shaft modules. For example, a shaft **3** that has a rack and rotator head assembly **37** may be interchanged with a shaft **3** having the same type of head assembly **37**, but with a different angle of curvature. Alternatively, a shaft **3** with a rack and rotator head assembly **37** may be interchanged with a shaft **3** having a wrap-around head assembly **35**. Similarly, different couplers **43** may be interchanged to facilitate the use of different bone anchor screws **5**.

<u>Cup and Washer Manual Bone Anchor Placement Device</u>

As with the previously disclosed manual bone anchor placement devices **1** and **36**, the cup and washer manual bone anchor placement device **52**, is configured to be substantially pistol- or gun-shaped, having a handle **2** with a gripping portion **26** and a lever **4**. In the cup and washer manual bone anchor placement device **52**, however, the "barrel of the gun" is formed by a driver rod **53** that extends through the handle **2** and is substantially perpendicular along its length to the longitudinal axis of the gripping portion **26** of the handle **2**.

Figures 22A and 22B show a cross-section of the cup and washer manual bone anchor placement device **52**. The driver rod **53** includes a smooth portion **54** and a lead screw portion **55** with integral single or multistart threads **55t**. The lead screw portion **55** may be integral with the smooth portion **54**. Alternatively, the lead screw portion **55** may be screwed onto threads or grooves at one of the ends of the smooth portion **52**. The lead screw portion **55** may extend from one end of the handle **2** to the other end of the handle **2** or the lead screw portion **55** may comprise a substantial portion of the driver rod **53**. As used herein, "a substantial portion" refers to greater than 50% of the length of the driver rod **53**. In a different embodiment of the invention, the driver rod **53** may be flat stock twisted into a spiral with a long pitch.

The lead screw portion **55** of the driver rod **53** further includes an engaging element **55e** at the end of the lead screw portion **55** distal to smooth portion **52** of the driver rod **53.** The engaging element **55e** engages with a coupling member **59**. The coupling member **59** has a mating portion **59m** for mating with a bone anchor screw **5** and an engaging portion **59e** for engaging with the engaging element **55e** of the lead screw portion **55**.

The position of the coupling member **59** relative to the lead screw portion **55** of the driver rod **53** may be controlled by means of a coupling member stop **59s**. A chuck **57** provided at the barrel end **56** of the handle **2** further secures coupling member **59** to the lead screw portion **55** of the driver rod **53**. Since the chuck **57** contacts both the lead screw portion **55** of the driver rod **53** and the coupling member **59**, any force transmitted through the driver rod **53** is also transmitted through the coupling member **59** to the bone anchor screw **5**. In a further embodiment of the invention, a rotatable twist lock **58** is provided, thereby supplying an additional means of securing the chuck **57** to coupling member **59**.

The rotary force mechanism in the cup and washer manual bone anchor placement device **52** includes cup and washer assembly **60**, which includes a cup **61**, a washer **62,** and at least one engaging pin **65**. The cup **61** is capable of axial movement along the lead screw portion **55** of the driver rod **53**, while the washer **62** is capable of both axial motion and rotational motion along the lead screw portion **55**.

Movement of the cup **61** is controlled by actuation of an action mechanism that includes a lever **4** and a force-translating member **64**. The force-translating member **64** has a first end **64f** and a second end **64s**. The first end **64f** of the force-translating member **64** is coupled to the

lever **4** at pivot point **9** while the second end **64s** is coupled to the side of the cup **61** by means of flanges **61f** on the cup. The flanges **61f** form a yoke that links the cup **61** to the force-translating member **64**. The cup **61** is thus free to ride on the lead screw **55** in response to movement of force translating member **64**.

The cup and washer manual bone anchor placement device **52** operates on the principle of a child's top. Applying a linear force on the lever **4** by squeezing it towards the gripping portion **26** of the handle **2** actuates the action mechanism. Linear force is transmitted from the lever **4** to the force-translating member **64** and is transmitted to cup **61**. In the embodiment of the invention shown in Figure 23, the cup **61** has two engaging pins **65** that fit into complementary holes **66** in the washer **62**. The cup **61** is capable of engaging and disengaging the washer **62** depending upon its direction of travel, while the washer **62** includes protrusions **67** that allow it to move along and follow the thread pitch of the threads **55t** of the lead screw portion **55** of the driver rod **53**. In the embodiment of the invention shown in Figure 23A, the lead screw portion **55** includes grooves **66g** complementary to protrusions **67** in the washer **62**. In the embodiment of the invention shown in Figures 24A and 24B, the engaging pins **65** of the washer **62** further include tangs **65t**, and the cup **61** includes ribs **71** that constrain the motion of the washer **62** further when the tangs **65t** of the washer **62** contact the walls of the ribs **71**.

Upon squeezing the lever **4**, the translating member **64** is driven forward, moving the cup **61** forward at the same time (see dashed arrows in Figures 22A and B). When the motion of the cup **61** is initiated, the washer **62** is forced by the lead screw portion threads **55t** into contact with the cup **61**. The engagement pins **65** of the cup **61** then engage with the washer **62**. Once engaged, the washer **62** is no longer free to rotate or spin on the lead screw portion threads **55t**. As the translational member **64**, cup **61**, and washer **62,** advance in a linear, forward direction, linear force from the force translating member **64** on the cup **61** is translated into rotary force upon the lead screw portion **55** of the driver rod **53**, causing the driver rod **53** and the coupling member **59,** which is coupled to it, to twist as the washer **62** follows the threads **55t** of the lead screw portion **55**. This twisting motion in turn applies a torque to a bone anchor screw **5** engaged by the coupling member **59**, thereby screwing the bone anchor screw **5** into bone.

On the lever return stroke, there is minimal linear force imposed upon the coupling member **59**. The cup **61** provides the washer **62** with clearance to disengage from the engaging

pins **65** of the cup **61** and to rotate freely as the washer **62** follows the threads **55t** on the lead screw portion **55** of the driver rod **53**. In a further embodiment of the invention, shown in Figure 22B, a return coil spring **68** may provided at the barrel end **56** of the handle **2** to further apply a return compressive force on the cup **61** and translating member **64** when the lever **4** is released.

By incorporating a 60-degree pitch angle and 3-start thread, the complete seating of a bone anchor screw **5** can take place in approximately 10 strokes of the lever **4**. Optimizing thread 55t design, lever 4 stroke and/or cup 61/washer 62 clearance can reduce the number of strokes.

It should be readily apparent to one of ordinary skill in the art that the engaging pins **65** may be provided on the washer **62** side rather than the cup **61** side and that the holes **66** may be provided in the cup **61**. The number of engagement pins **65** may also be varied. The engaging pins **65** may be an integral part of the washer **62** or cup **61**, or may be removable from the washer **62** or cup **61**. In addition, the number of starts in the multistart thread **55t** of the lead screw portion **55** of the driver rod **53** may be varied from one through what ever number is dimensionally practical for the driver rod **53** diameter.

In a further embodiment of the invention as shown in Figures 22A, 22B, 24A, and 25B, a cover plate **63** is provided at the rim **69** of the cup **61** to contain the washer **62** within the cup **61** and to permit only minimal travel space for the washer **62** to move in when it is drawn free from the engaging pins **65** of the cup **61**.

As with the previously disclosed manual bone anchor placement devices **1** and **36**, the cup and washer manual bone anchor placement device **52** may be used with a bone anchor screw **5** with a pre-attached suture **7** that may be enclosed within a sleeve **24** press-fitted into a groove **23** cut into handle portion **2**. The mating portion **59m** of the coupling member may be configured to mate with a variety of bone anchor screws **5**, and may include a shaft configured in a shape complementary to a recess in a bone anchor screw **5** or may include a recess complementary to a shaft in a bone anchor screw **5**. As in the previously disclosed devices **1** and **36**, the cup and washer manual bone anchor placement device **52** may include a modular design allowing for the interchange of different types of coupling members **59**. The handle portion **2** may also be configured to include two separable halves that are able to snap-fit together,

allowing removal of one driver rod and/or cup and washer assembly and replacement with another.

Self-Tapping Bone Anchor Screw

Figure 26 shows a bone anchor screw **5** according to one embodiment of the invention. As shown in the Figure 26, the threads of the bone anchor screw **5** are of buttress form. The forward face **72** of the screw thread is perpendicular to the longitudinal axis **73** of the bone anchor screw **5** while the back face **74** of the screw thread is at an acute angle relative to the longitudinal axis **73** of the bone anchor screw **5**. The threads extend to the tip of the screw shank **75**, reducing the amount of torque required to seat the bone anchor screw **5**. In one embodiment of the invention, the back face **74** of the screw thread is at about a 30-degree angle relative to forward face **72** of the screw thread.

The base **76** of the bone anchor screw **5** shown in Figure 26A has an eyelet **77** that is circular and has micropolished edges. In another embodiment of the invention, the eyelet **77** at base **76** may be teardrop shaped, or ellipsoidal. Other configurations may be used so long as the edges are rounded so as not to damage the suture **7**. Micropolishing the eyelet **77** rounds the edges and reduces load to the suture **7** that may be caused by twisting (torsional load) during insertion, the user tugging on the suture **7** to test seating of the screw, and bodily movement while the anchor screw and suture are in place.

According to a further embodiment of the invention, kits including the disclosed self-tapping bone anchor screw may be provided for the convenience of the user. In one embodiment of the invention, a kit is provided, including at least one of: 1) a flexible, molded sleeve **24** for enclosing a suture **7**, 2) a retaining clip **27** for preventing the suture **7** from slipping out of the sleeve **24**, 3) a buttress-shaped bone anchor screw **5** with a micropolished eyelet **77** for receiving the suture **7**, and 4) suture material, which may or may not, be pre-attached to the bone anchor screw **5**. The kit may include any one of these elements or combinations thereof.

Recessed Bone Anchor Mount

The recessed bone anchor mount is designed to be used in conjunction with the various bone anchor placement devices described hereinabove; however, the recessed mount is not limited to use with only those types of bone anchor placement devices.

Figure 27A is a perspective view of one embodiment of a bone anchor placement device **210** constructed according to the present invention. The anchor placement device **210** includes a handle **212**, and a shaft **214** extending in a distal direction from the handle **212**. A head assembly **216** is disposed at a distal end **218** of the shaft **214**, and defines a core **220** that may be further defined by driver guide **300**. A recessed anchor mount **222** is fixedly engaged within the core **220**. In one embodiment, the handle **212** includes an actuator **224** for actuating a mechanism **226** for advancing or retracting the anchor mount **222**.

The handle **212** serves as a gripping area for a surgeon, and is preferably of a size that makes it easily grippable by a user. A handle that is at least about 4 inches (100 mm) in length has been found to work well. The handle **212** may be made of any relatively firm material, including plastic or metal. For example, the handle **212** may be made of plastic, aluminum, stainless steel, or titanium. Those skilled in the art will appreciate that a wide range of other materials may also be employed. The handle **212** may be configured in any of a variety of shapes compatible with vaginal insertion of the anchor placement device **210**. In the embodiment shown in Figure 27A, the handle **212** tapers towards the proximal end to facilitate gripping by the user. Preferably, the handle **212** is provided with knurling or other surface texturing to produce a high friction, non-slip gripping surface.

The shaft **214** extends in a distal direction from the handle **212**, and is adapted for releasably engaging a bone anchor **230**. The shaft **214** has a distal end **218**, and a proximal end **228**. The shaft **214** may be curved or angled at one or more portions to facilitate correct placement of the bone anchor placement device **210** to a proper bone anchor insertion site. The shaft **214** may be made of any of a variety of materials; including steel, stainless steel, aluminum, titanium, and plastic, but is preferably made of stainless steel. The shaft **214** may have a variety of cross-sectional shapes including round, elliptical, rectangular, hexagonal, or triangular, but preferably the shaft **214** has a round cross-section.

The length of the shaft **214** is consistent with transvaginal delivery of a releasable bone anchor **230** and may be of an appropriate length to permit access of the bone anchor **230** to the desired location. The cross-sectional dimension of the shaft 14 is a function of the force-translating mechanism (variations of which are described hereinabove) and the actuator mechanism **226** and may range from about 0.2 to about 1.0 inch in diameter.

Figure 28A is an enlarged view of one embodiment of a recessed anchor mount **222** constructed according to the present invention and of a bone anchor **230** for attachment to the anchor mount **222**. The mount **222** has a distal end **223** and a proximal end **229**. In one embodiment, the mount **222** has a hexagonal interior lumen **232**, and a matching or complimentary outer surface **234**. The mount **222** may have other configurations for its interior lumen **232** and outer surface **234**, such as a rectangular, pentagonal, octagonal, or round. Figure 28B depicts an end view of an alternative anchor mount **222** with a primarily round outer surface **234** and a groove **235** for interlocking with a pin or protuberance (not shown) within the driver guide **300**. Figure 28C depicts an end view of an alternative anchor mount **222** with a primarily round outer surface **234** and a flat surface **237** for interlocking with a mating flat surface (not shown) within the driver guide **300**.

A variety of bone anchors **230** can be used. In one embodiment, the bone anchor **230** includes a spear member **236** that is able to pierce and securely engage a bone or bone tissue. The spear member **36** has a generally cone shaped head portion **238** which is used to pierce the bone and a shaft portion **240** with an eyelet **242** therethrough for receiving and holding one or more suture strands **241**.

The outer surface of the shaft portion **240** of the anchor **230** is shaped to fit within the anchor mount **222**, and is adapted to rotate with the anchor mount **222**. In preferred embodiments, the shaft portion **240** has the eyelet **242** formed radially therethrough proximate one of its ends. The eyelet **242** may be of any shape and is of a sufficient size to permit a suture strand or strands **241** to pass therethrough. The circumference of each outer end of the eyelet **242** is preferably chamfered or grounded to provide a beveled surface. A beveled surface provides a generally smooth surface for contacting a suture strand 41 that has been passed through the eyelet **242**. The eyelet **242** is preferably located on the shaft portion **240** of the anchor **230** such that the transverse axis of the eyelet **242** intersects the longitudinal axis of the spear member **236**.

The generally cone-shaped head portion **238** of the spear member **236** is located at an end of the shaft portion **240** opposite the end having the eyelet **242**. The apex of the cone-shaped head portion may terminate in a sharp tip or point **243** that is suitable for being driven into bone. The diameter of the cone-shaped head portion **238** increases, when viewed along its longitudinal direction rearwardly from the point **243**, towards the shaft portion **240**.

Any known materials suitable for orthopedic anchor devices may be employed to construct the bone anchor **230** of the present invention. Preferably, the bone anchor **230** is formed from a plastic polymer or metallic material possessing sufficient strength to penetrate and anchor to bone. Such materials include titanium, 316 LVM stainless steel, CoCrMo alloy, Nitinol alloy, or polymers, for example, polyglycolic acid (PGA) with or without absorbability properties. Preferably, the bone anchor is made of titanium.

Figure 29A is an enlarged view of one embodiment of the head assembly **216** of the anchor placement device **210** of Figure 27A, and a recessed anchor mount **222** housed within the head assembly **216** in a retracted position.

The head assembly **216** is capable of releasably engaging a bone anchor mount **222** and is connected to a mechanism **226** that translates axial motion to the mount **222** to advance or retract the anchor **230**. The head assembly **216** defines a hollow core **220** that may be further defined by driver guide **300**. The interior dimensions of the core **220**, or driver guide **300**, permit a recessed anchor mount **222** to be moveably fitted therein. In preferred embodiments, the interior dimensions of the core **220**, or driver guide **300**, are only slightly larger than the exterior dimensions of the anchor mount **222**. The length of the anchor mount **222** is about 0.12 to about 0.25 inches, preferably about 0.15 to about 0.20 inches, and more preferably about 0.185 inches. The length of the driver guide **300** is essentially the length of the anchor mount **222** and the anchor **230**.

In preferred embodiments, the core **220** has a shape complementary to the proximal end **229** of the anchor mount **222**, so as to permit the mount **222** to engage the driver guide **300**. For example, the driver guide **300** and the proximal end **229** of the anchor mount **222** may be square, rectangular, pentagonal, triangular or hexagonal in cross-section. In some embodiments, the driver guide **300** and the proximal end **229** of the anchor mount **222** have hexagonal cross-sections; however, those skilled in the art will appreciate that numerous shapes may be employed

and the present invention specifically contemplates any such shape. In some embodiments, driver guide **300** includes a stop **247** disposed on the interior surface of the driver guide **300**. In alternative embodiments, the stop is disposed on the mechanism **226** and limits the travel of the mechanism **226**, and thereby limits the travel of the anchor mount **222**. The stop **247** prevents driving the bone anchor **230** too far into the bone.

In some embodiments, the mechanism **226** that translates motion to the mount **222** is a push wire **246a**. Alternatively, the mechanism **226** could be a pull wire **248b** as depicted in Figures 30A and 30B. The mechanism **226** operates on the same principle whether a push wire **246a** or a pull wire **246b** is used, and the following description is directed only to a push wire **246a** for simplicity. The push wire **246a** is coupled to the anchor mount **222** via a point contact, as shown in Figure 29C, to advance or retract the anchor mount **222**. Alternatively, the push wire **246a** may be secured to the anchor mount **222**. For example, the push wire **246a** may be welded or crimped to the anchor mount **222**, in which case the push wire **246a** must be able to twist and roll freely within the shaft **214**. In such embodiments, the actuator to push wire connection is preferably non-fixed. In alternative embodiments, the push wire **246a** may be coupled to the anchor mount **222** via a free-floating mechanism **247**, as shown in Figure 29D.

As shown in Figures 27A and 30A, the push/pull wire **246a,b** is a substantially linear member that extends from the handle **212**. The push/pull wire **246a,b** is made of a high tensile material. Suitable push wire materials include metals, plastics, and reinforced polymers. In preferred embodiments, the push/pull wire **246a,b** is made of spring steel, or superelastic nitinol. In some embodiments, a groove or channel **248** is cut into the outer surface of the shaft **214**, extending in a line substantially parallel to the longitudinal axis of the shaft **214**. Alternatively, the groove or channel may be otherwise formed as part of the shaft **14** and may completely encapsulate the push/pull wire **246a,b** and/or mechanism **226**, for examples see Figures 27B-27E. The push/pull wire **246a,b** is situated within the channel **248** disposed on the shaft **214**. In some embodiments, an actuator **224**, such as a button, lever, or trigger disposed on the handle **212,** activates the push/pull wire **246a,b**. Force exerted on the actuator **224** is translated to the anchor mount 222 as linear force through the push/pull wire **246a,b**.

During insertion of the device **210** into the body, the anchor mount **222,** as well as an attached bone anchor **230**, remain in a recessed position, as shown in Figure 29A. The sharp tip

243 of the anchor **230** therefore remains unexposed to bodily tissue. The likelihood of tearing and scraping of tissue, as well as injury to delicate abdominal organs, is thereby reduced. Because the bone anchor **230** remains protected within the hollow core **220** of the head assembly **216**, the likelihood of dislodgment of the bone anchor **230** during insertion is also reduced. The need for protective covers or sheaths for the purpose of shielding the tip **243** of the anchor is also reduced. Furthermore, when the anchor mount **222** is recessed, the profile of the head assembly **216** is reduced in comparison to the configuration where the anchor mount **222** protrudes from the head assembly **216**. Therefore, a smaller vaginal incision is required, as compared to the situation where a protective shroud or cover is provided for the bone anchor **230**.

Figure 29B is an enlarged view of one embodiment of a head assembly **216** of an anchor placement device **210** of Figure 27A, and a recessed anchor mount **222** protruding from the head assembly **216**.

In operation, when a force is exerted on the actuator **224** by pushing, pulling, or otherwise actuating the actuator **224**, the exerted force is translated as a linear force through the push/pull wire **246a,b** to the anchor mount **222**. Optionally, the actuator **224** can be locked in place to prevent the anchor mount **222** from retracting. As the exerted linear force is transmitted to the anchor mount **222** through the push/pull wire **246a,b**, the anchor mount **222** advances linearly, moving within the driver guide **300**. The attached bone anchor **230** may advance with the anchor mount **222** until halted by the optional stop **247** disposed within the driver guide **300**. In an alternative embodiment, the mechanism **226** may also actuate a force-translating mechanism (variations of which are described hereinabove), and thereby turn the anchor mount **222** in response to the applied force.

Having thus described certain embodiments of the present invention, various alterations, modifications, and improvements will be obvious to those skilled in the art. Such variations, modifications and improvements are intended to be within the spirit and scope of the invention. The materials employed, as well as their shapes and dimensions, generally can vary. Accordingly, the foregoing description is by way of example only and is not intended to be limiting.

What is claimed is: